April 29, 2005

Marcia Hardy, DVM, PhD
Albemarle Corporation
451 Florida Street
Baton Rouge, LA 70801-1765

Dear Dr. Hardy:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for 3,4,5,6-Tetrabromo-1,2-benzenedicarboxylic acid 2-(2-hydroxyethoxy)ethyl 2-hydroxypropyl ester (tetrabromophthalic acid diester, CAS No. 77098-07-8), posted on the ChemRTK HPV Challenge Program Web site on March 9, 2004. I commend Albemarle Corporation and Great Lakes Chemical Corporation for their commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA has reviewed this submission and has reached the following conclusions:

1. Substance identity. The substance is a mixture of the monomer and its oligomers. The submitter needs to provide information on the typical concentration ranges of monomer, dimer, trimer, etc.

2. Physicochemical Properties and Environmental Fate. EPA agrees with the submitter's proposal to test for the vapor pressure, water solubility, water stability and biodegradation endpoints. The submitter provided an estimated melting point value of 230°C. Estimated melting point values above 0 °C are generally inadequate for the purposes of the HPV Challenge Program. The submitter needs to provide a measured melting point (or freezing point) following OECD test guidelines.

3. Health Effects. The acute toxicity data provided by the submitter are adequate for the purposes of the HPV Challenge Program. In the gene mutation test, the submitter needs to provide information on controls that were used so that the reliability of the data can be evaluated. EPA agrees with the submitter's proposal to test for the chromosomal aberration toxicity endpoint. However, EPA disagrees with the submitter's tiered approach in which testing for reproductive and developmental toxicity depends on results of a repeated-dose toxicity test. For the HPV Challenge Program, the submitter needs to provide adequate data for all endpoints. Therefore, data need to be provided for the repeated-dose/reproductive/developmental toxicity endpoints, using the commercial product, according to OECD TG 422.

4. Ecological Effects. EPA agrees with the test plan to conduct acute toxicity testing for invertebrate and algae toxicity endpoints. EPA reserves judgement on data adequacy for the acute fish toxicity endpoint pending the submission of the following missing data elements from the robust summary: test substance purity, DO, TOC, water temperature, water hardness, number of replicates, and number of fish per replicate.

EPA will post this letter on the HPV Challenge Web site within the next few days. We ask that Albemarle and Great Lakes Corporations advise the Agency, within 60 days of this posting on the Web site, of any modifications to their submission. Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact Mark Townsend, Acting Chief of the HPV Chemicals Branch, at 202-564-8617. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: M. E. Weber
J. Willis